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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,261	12/06/2000	Joel F. Habener	17633/1230	9060

29933 7590 10/24/2005

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT PAPER NUMBER

1633

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,261

Applicant(s)

HABENER ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,21-29 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43 is/are allowed.
- 6) ☒ Claim(s) 19,21-29 and 44 is/are rejected.
- 7) ☒ Claim(s) 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment received on 8/12/05 has been entered. Applicant's arguments and the second Declaration under 37 CFR 1.132 by Joel F. Habener have also been entered. Claims 1-18, 20, and 30-41 are canceled. Claims 19, 21-29, and 42-44 are currently pending and under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in previous office actions.

Priority

Priority to applicant's provisional applications is acknowledged.

Claim Rejections - 35 USC 112

The rejections of claims 43-44 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of applicant's amendment to the claims.

Claim Rejections - 35 USC 102

The rejection of claims 24-29, and 44 under 35 U.S.C. 102(b) as being anticipated by WO 97/15310 (5/1/97), hereafter referred to as Peck et al., is maintained. Applicant's arguments and the second Declaration by Dr. Habener have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the islet producing stem cells disclosed by Peck et al. are not identical to the isolated nestin-positive pancreatic stem cells as claimed because the declaration by Dr. Habener asserts that nestin-positive cells are believed to represent only 0.2-5% of cells in the pancreas, such that the culture method taught by Peck et al. would not give rise to a population wherein at least 30% of the cells are nestin positive, and Peck et al. further does not include a selection step where nestin-positive cells are selected and then grown. The applicant's arguments are based on the definition of an "isolated nestin-positive pancreatic stem cell" found on page 11 of the specification, which states that, "[i]solated stem cells will generally be at least 30%, 40%pure". In response, the definition provided on page 11, by stating "generally" does not exclude cell populations in which there are less than 30% nestin positive cells as meeting the limitations of an isolated, nestin-positive stem cells. Further, the claim as written do not set forth any particular limitations as to the purity or percent purity of the cells as claimed. In addition, the second declaration by Dr. Habener has been carefully considered, but the examiner cannot find any statement in the declaration by Dr. Habener that nestin-positive cells only represent 0.2-5% of cells in the pancreas. Dr. Habener does state on page 2 that using isolated human pancreatic islet cells, cell culture of these islets resulted in less than 10% attachment to a culture dish and that of the cells attached some were nestin positive and some were not; however, no

particular percentages were given by Dr. Habener. In addition, the method used by Peck et al. to isolate pancreatic stem cells teaches that the cell culture conditions used severely comprises the growth of differentiated or mature cells present in the culture such that IPSCs survive whereas most of the differentiated cells do not survive (see Peck et al., page 14). Following the directions, the IPSC population obtained would be reasonably expected to be substantially greater than 30%.

The applicant further argues that the office has not provided extrinsic evidence that the IPSCs of Peck et al. express nestin as required to make a case for inherency, citing *In re Rijckaert*, *In re Oelrich*, and *In re Robertson*. In response, the rejection of record provides specific reasoning why the nestin expression would be inherent to the IPSCs taught by Peck et al. as required by MPEP 2112. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). In the instant rejection, the examiner relies on the fact that the IPSCs of Peck et al. appear to have the identical functional characteristics as the cells claimed, i.e. they possess the ability to differentiate into pseudo-islets in culture and do not express markers associated with differentiated/mature pancreatic islet cells. It is noted that page 11 defines one embodiment of a pancreatic stem cell as a cell that has been isolated from pancreatic tissue, and page 16 of the specification states that pancreatic stem cells are characterized by "one or more" of a list of characteristics that include the "ability to differentiate into pseudo-islets in culture". Thus, the cells taught by Peck et al. meet the definition of pancreatic stem cells set forth by the applicants. As such, the rejection of record does in fact set forth specific reasoning to support that the cells taught by Peck et al. inherently

express nestin. The applicant is further reminded that there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003)

Finally, as noted in the previous office action, the office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). Applicant's declaration, while setting forth their own specific methodology used to isolate nestin positive pancreatic stem cells does not compare the resulting population with that of Peck et al. and demonstrate that the iPSCs of Peck et al. do not express nestin.

Thus, in the absence of evidence to the contrary, the office maintains that the human pancreatic stem cells disclosed by Peck et al. anticipate the instant invention as claimed.

Double Patenting

The provisional rejection of claims 24-28 under 35 U.S.C. 101 as claiming the same invention as that of claims 39 and 43 of copending Application No. 09/963,875, hereafter

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referred to as the '875 application, is maintained. The applicant states that claims 39 and 43 of the copending application will be amended; however, no such amendments have been filed as of the preparation date of this office action. As such the provisional rejection stands. However, at such time that this instant provisional rejection is the only rejection remaining in this application and the copending application has not been issued, the provisional rejection of the claims will be withdrawn in this application based on the earlier filing date of the instant application compared to the 09/963,875 application, see MPEP 804 (1)(B)(2).

This rejection remains a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 19, 21-23, 29, and 43-44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39-43 of copending Application No. 09/962,875, hereafter referred to as the '875 application, is maintained. The applicant states that a terminal disclaimer will be submitted by the applicant upon the indication of allowable subject matter. However, at such time that this instant provisional rejection is the only rejection remaining in this application and the copending application has not been issued, the provisional rejection of the claims will be withdrawn in this application based on the earlier filing date of the instant application compared to the 09/963,875 application, see MPEP 804 (1)(B)(1). A terminal disclaimer will not be required in this application unless the copending application is issued as a patent prior to the indication of allowable subject matter in this application.

This rejection is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claim 42 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

Claim 43 is free of the prior art of record and considered allowable at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

